College of Medicine

Surgery Department

Determinants of anastomotic leakage among adult bowel surgery patients at Queen Elizabeth Central Hospital, Malawi

By

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DECLARATION

I, Rodrick Vale Banda, hereby declare that this thesis is my original work and has not been presented for any other awards at the University of Malawi or any other university.

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ABSTRACT

Background:

Anastomotic leakages are major complications of bowel surgery with significant implications on patients' health, prognosis and on health care costs as well. The prevalence of anastomotic leaks (AL) is between 0.5% and 21% after colon and rectal resections [1–5]. The incidence is between 1% and 12% overall and up to 10% to 14% in low colorectal resections [5-8].

Problem statement

In Malawi as in other Sub-Saharan countries, there is limited data on AL. This study seeks to determine the factors predisposing to AL among adult bowel surgery patients at Queen Elizabeth Central Hospital (QECH)

Main Aim

- To determine the risk factors for AL among adult bowel surgery patients at QECH

Specific objectives

- To determine the incidence of bowel AL among adult patients at QECH
- To determine the difference in outcomes of bowel surgery performed by surgical trainees and consultant surgeons
- To determine the 30-day mortality post bowel AL

Methodology

The study was a retrospective cohort study of the risk factors involved in the occurrence of AL within 30 days post-surgery. Patient's files were retrieved from the QECH health information management systems for the period January 2008 to December 2016.

Results:

Over the study period, 185 patients with intestinal anastomosis were identified; the overall leak rate was 16.8% (31/185) and 30-day mortality rate post AL was 35.5% (11/31). In bivariate analysis, 5 factors were associated with AL. Out of these 5 factors, 3 were found to be independent determinants of AL using a logistic regression model: intraperitoneal local sepsis (Relative risk [RR] 7.2, 95%confidence interval [CI] 2.81-17.5), Haemoglobin level ([<10g/dl] RR 4 ,95% CI 2.167 – 7.5) and Surgeons experience(Trainee/ expert) (RR 1.4 , 95% CI 1.143-1.957)

CONCLUSIONS:

The knowledge of factors associated with anastomotic leakage after intestinal anastomosis can be modified to reduce AL and improve AL outcomes in our setting

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List of Abbreviations and Acronyms:

COMREC:	College of Medicine Research and Ethics Committee
MMED:	Master of Medicine
SPSS:	Statistical Package for Social Sciences
QECH:	Queen Elizabeth Central Hospital
AL:	Anastomotic leak

Definitions:

Anastomosis Surgical connection of two end bowels

Ileacolic anastomosis: Surgical connection between ileum and colon

Adult : Person of 18years and above

Child : Person of less than 18 years

Defunctioning stoma: The surgical exteriorisation of the bowel after segmental resection and before re-anastomosis.

CHAPTER 1

1. INTRODUCTION

A failed anastomosis will result in one of the most serious complications of gastrointestinal surgery; an anastomotic leak. The prevalence of anastomotic leakage (AL) has been reported to be between 0.5% and 21% after colon and rectal resections [1–5]. The incidence of clinically significant AL after colorectal surgery is between 1% and 12% overall and up to 10% to 14% in low colorectal resections [5-8].

The consequences of an anastomotic leak are serious. There is a significant associated morbidity, prolonged hospital stays, and a mortality rate which exceeds 20% in several series [8-14]. To mitigate the sequelae of an anastomotic leak surgeons may choose to create a defunctioning stoma or to avoid an anastomosis altogether by forming an end stoma.

A defunctioning stoma decreases the severity of sepsis due to anastomotic leak, reduces the need for emergency reoperation and reduces mortality [16-19]. However, forming a defunctioning stoma is a difficult decision and one that patients and surgeons, will naturally wish to avoid [20, 21]. Stomas carries a significant morbidity like, stoma retraction, necrosis, prolapse or stenosis. Furthermore , Stomas reduce the quality of life for the patient and stoma closure requires a second operation at a later date, this requires an additional length of stay and cost[20,21].

In Malawi, as in other Sub- Saharan countries there has been very limited data published that has reported on the risk factors of AL. As a result, there is no established assessment of risk factors for AL before surgical treatment and there are no established guidelines for its management. The results of this study will inform the surgery department and the QECH about the incidence of the AL and the risk factors predisposing to AL at QECH. The knowledge gathered will be the key to its early detection and improving decision making on whether to defunction the patient when the anastomosis is in question or to avoid an anastomosis altogether by forming an end stoma. Furthermore, the surgeon will be able to anticipate postoperative complications and to manage preoperative risk factors.

CHAPTER 2

OBJECTIVES

Main Aim

- To determine the risk factors for anastomotic leak among adult bowel surgery patients at QECH

Specific objectives

- To determine the incidence rate of bowel anastomotic leak among adult patients at QECH
- To determine the difference in outcome of bowel surgery performed by surgical trainees and consultant surgeons
- To determine the 30-day mortality rate post bowel anastomotic leak

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CHAPTER 3

LITERATURE REVIEW

Anastomotic leak is serious complication of bowel surgery with serious consequences. The rates of morbidly and mortality increases significantly after anastomotic dehiscence, with mortality reported rates in literature of between 12% and 27% [52]. The reported rates of anastomotic leak vary between 1% and 30%, although experienced colorectal surgeons often quote 3% to 6% as an acceptable overall leakage rate [52].

The table below shows anastomotic leak in colorectal surgeries reported by various authors.

Table 2.1. showing AL in colorectal surgeries by different authors [52]

First author	No. of Patients	Leak rate (%)
Biondo	211	5.7
Docherty	652	4.4
Alves	707	6
Konishi	391	2.8
Hyman	1,223	2.7
Lipska	541	6.5
Branagan	1,834	3.9
Sorenson	333	15.9
Wong	1,066	3.8
Platell	1,639	2.4
karanjia	216	11
Law	196	10.2
Gastinger	2,729	14
Rullier	131	19
Vignali	284	7.8

There is not enough data on small bowel anastomotic leak. Few studies have reported the AL rate of 2 % to 7 % for small bowel operation if the surgery was done by an experienced surgeon [22-25].

Data on anastomotic leak both locally and in Africa is very sparse.

3.1. Definition and manifestations

The criteria for defining a leak vary greatly from serie to serie [24]. In a systematic review of studies measuring the anastomotic leak rate after gastrointestinal surgery, Bruce et al. noted that there was a total of 56 separate definitions of an anastomotic leak in the 97 studies reviewed [27]. The majority of reports define an anastomotic leak using clinical signs, radiographic findings, and intraoperative findings [28, 29].

The clinical signs include:

- Pain
- Fever
- Tachycardia
- Peritonitis
- Feculent drainage
- Purulent drainage

The radiographic signs include:

- Fluid collections
- Gas containing collections

The intraoperative findings include:

- Gross enteric spillage
- Anastomotic disruption

3.2. Diagnosis

Most anastomotic leaks usually become apparent between 5 and 7 days postoperatively. One study reported that almost half of all leaks occur after the patient has been discharged, and up to 12% occur after postoperative day 30[25]. Late leaks often present insidiously with low-grade fever, prolonged ileus, and nonspecific symptoms attributable to other postoperative infectious complications. Small, contained leaks present later in the clinical course and may be difficult to distinguish from postoperative abscesses by radiologic imaging, making the diagnosis uncertain and underreported

3.3 Risk factors

Risk factors can be categorized as patient-specific, intraoperative, and specific for low rectal anastomosis.

3.2.1 Patient-specific risk factors include age above 75 years, malnutrition, steroids, tobacco use, leucocytosis, cardiovascular disease, alcohol use, Anaemia, American Society of Anaesthesiologists (ASA) score, and diverticulitis [34].

3.2.2. Intraoperative risk factors

- **American Society of Anaesthesiologists (ASA) score**

  The ASA physical status examination is used by anaesthesiologists to classify preoperative physical condition of surgical patients. The scale ranges from 1, signifying a normal, healthy patient, to 5, representing a patient not likely to survive 24 hours. In a multivariate analysis of leaks in 1,417 colon resections above the peritoneal reflection, ASA grade of 3 to 5 was statistically significant ($p = 0.0001$) risk factor for clinical anastomotic leak [34].

  ASA score 3 was a substantial risk factor, specifically in left-sided colon anastomotic leaks. Comorbid conditions as represented by an ASA score 3, are one method to indicate patients at higher risk for colonic anastomotic leaks. Comorbid conditions, such as diabetes mellitus, hypertension, and cardiac disease all represent conditions that affect ASA status and can cause impaired circulation at the microcirculation required for a healthy anastomosis [34].

- **Emergent surgery** — the same retrospective review found a significantly increased risk of the leak with emergency surgery after an intraperitoneal anastomosis compared with elective surgery (4.4 versus 1.0 %) [34]. For patients with both an ASA score Grade III to V and an emergency operation, the risk of an anastomotic leak was 8.1 % [34].

- **Prolonged operative time** — A prospective study of 391 elective colorectal resections identified a significantly higher leak rate when the operative procedure was ≥4 hours in duration compared with shorter procedures (5.1 versus 0.5 %) [31]. More difficult dissections and anastomoses were attributed to the longer operating times and increase in anastomotic leaks.

- **Local sepsis -** The presence of local sepsis (e.g. perforated diverticulitis, a perforated colorectal cancer, colorectal trauma, faecal contamination during colorectal surgery) causes the reduction in collagen at anastomotic site. This may result in higher anastomotic dehiscence rate [53].

- **Hand-sewn ileocolic anastomosis** — In a meta-analysis of six trials with 955 participants with benign and malignant disease, hand-sewn anastomoses were associated with a significantly higher rate of overall anastomotic leaks compared with stapled ileocolic anastomoses (6.0 versus 1.4 percent) [36].

3.2.3 Specific for low rectal anastomosis

- **The distance of the anastomosis from the anal verge** — Patients with a low anterior resection and an anastomosis within 5 cm from the anal verge are the highest risk group for an anastomotic leak [30, 31]. In the above-mentioned series of 1639 procedures, the risk of a leak was highest (8 percent) with ultra-low anterior anastomoses [30].

- **Anastomotic ischemia** — Two prospective studies using laser Doppler flow metry assessed blood flow to the colon and rectum before and after mobilizing, dividing, and anastomosing the colon [24-33]. A decrease in colonic tissue perfusion proximal to the anastomotic site, at the anastomotic site, and at the rectal stump was reported. The magnitude of the decrease in blood flow correlated with the subsequent development of an anastomotic leak.

- **Male gender** — In a prospective study of 196 patients undergoing rectal cancer resections, multivariate analysis showed a significantly higher rate of anastomotic leak in men [28] It is attributed to a narrow male pelvis which makes the anastomosis technically more challenging [34].

3.3 Consequences of the leak

Anastomotic leaks are often life-threatening complications with a mortality rate often reported in the literature to be in the 12-27% [37-41]. The mean length of stay in the hospital for patients with AL has been described between 36 and 39 days, approximately 4 times longer than for patients without leak [38,43]. Multiple reoperations and stoma creation are often necessary to control the leak, which significantly increases health risks and health care costs up to 5 times that of patients with no leak [42].

3.4 Treatment of anastomotic leak

The best option is to prevent AL from happening. Attention to details such as assuring a tension-free anastomosis, good blood supply and avoidance of an unduly prolonged operation with excessive blood loss can minimise the leak rate. The low leak rates reported by experienced surgeons in large series of carefully followed patients suggest that many leaks may be preventable.

Furthermore, some patient related risk factors may be addressed prior to surgery to minimise the risk of a post-operative leak. Patients can be counselled about smoking cessation and nutritional status restored where appropriate and possible. Post-operatively, the use of vasopressors may cause local tissue ischaemia and increase the risk of an anastomotic dehiscence. In a recent clinical series, the use of vasopressors increased the anastomotic leak rate threefold in a dose dependant manner.

CHAPTER 4

METHODOLOGY

4.1. Study design

This was a retrospective cohort study targeting adult (18years and above) patients who had bowel resection and anastomosis between January 2008 and December 2016 at Queen Elizabeth Central Hospital (QECH). The case files were identified by going through the electronic surgical database that contains all the surgical cases. Patients who had bowel resection and anastomosis were selected and their case files were retrieved from the QECH health management information system (HMIS). The following variables were extracted from the files, hospital number, age, sex, area of residence, admission date, discharge date, pre-operative diagnosis, haemoglobin level, intraoperative findings, ASA grade, HIV status, surgical intervention, anastomotic leakages upon the clinical picture (abdominal pain, fever, tachycardia, abdominal tenderness, enteric content discharge through the wound) and entered in SPSS version 20 (Refer to appendix 1 for details of the data collection form).

The sampled cases were grouped as those who developed anastomotic leak post bowel surgery as group A, and those without anastomotic leak post bowel anastomosis as group B(Figure 1).

We then looked at the distribution of various patient characteristics especially those known to be risk factors for anastomotic leak in the two groups to determine predictors of anastomotic leak in our study population. Factors associated with anastomotic leak with a p-value of less than 0.1 in bivariate analysis, were included in the final multiple logistic regression model. Those that achieved a p-value of less than 0.05 were confirmed as risk factors of anastomotic leak in our population.

The following diagram is a visual representation of the grouping

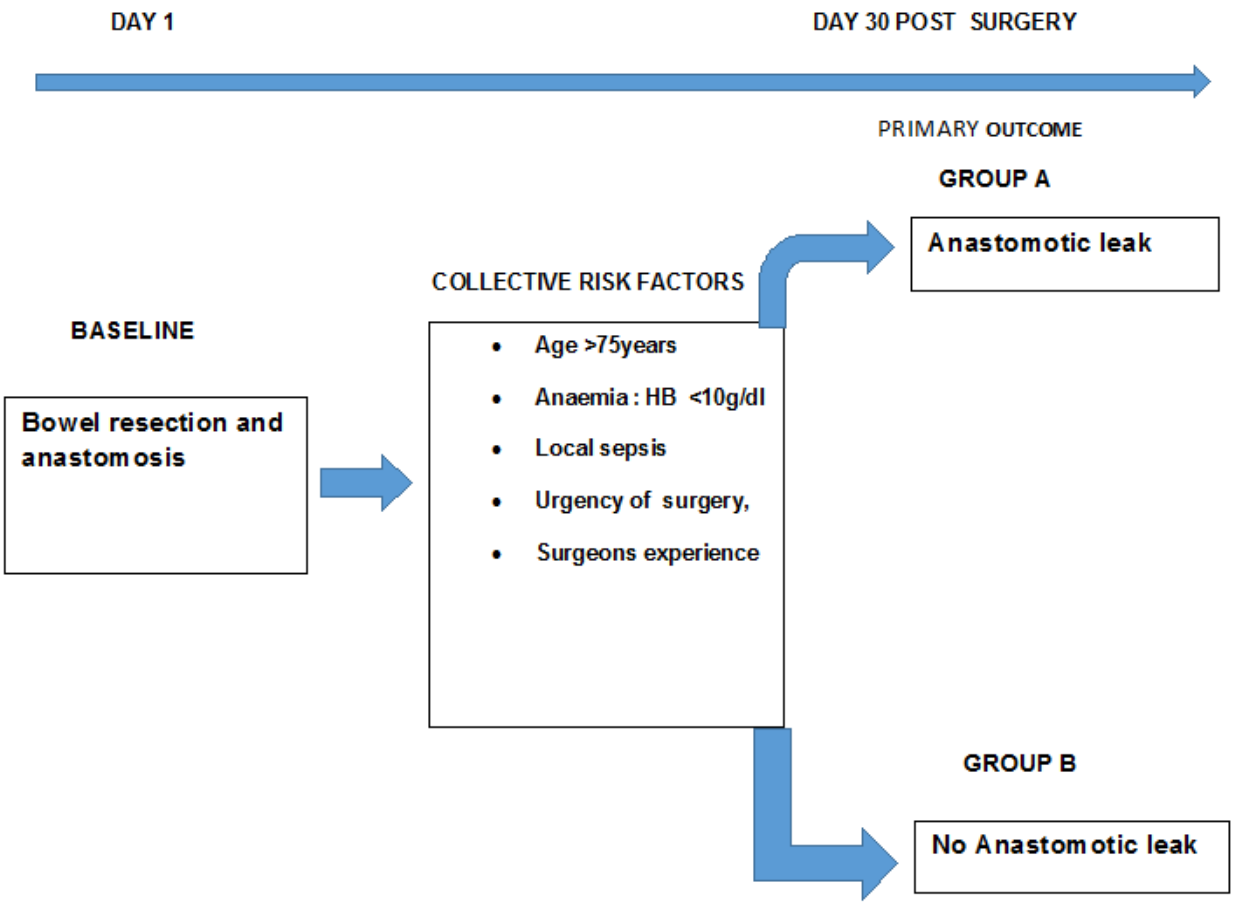

Figure 1: Patients recruitment, risk factors for anastomotic leak and expected outcomes

The expected primary outcome was anastomotic leak post bowel anastomosis and the secondary outcome was death post bowel anastomosis leak

Anastomotic leak in this study was defined as:

- leakage of bowel content and/or gas from the surgical connection between the 2 bowel ends into the abdomen or pelvis with either spillage and/or fluid collection around the anastomotic site or extravasation through a wound, drain site, or anus;
- Clinical manifestation causing fever, abscess, septicemia, peritonitis, and/or organ failure

Within the first 30 days after surgery.

The anastomotic risk factors in this study were defined as:

- Age more than 75years
- Anaemia: hemoglobin level of less than 10g/dl
- Local sepsis; i.e. intraoperative finding of pus, fecal contamination or gangrenous bowel
- Urgency of the surgery, i.e. emergency versus elective
- Level of surgeon's experience i.e. consultant/specialist versus trainee
- HIV positive status
- ASA grade III, IV and V

Inclusion Criteria includes:

i. The study included all adult patient (18years and above) who were operated at QECH and they had bowel resection and anastomosis.

Exclusion criteria include:

i. All patients who had no bowel resection and anastomosis

ii. All patients below 18 years

iii. All patient who had bowel anastomosis but also had a defunctioning stoma

iv. All patients who had bowel perforation oversewn.

4.2. Study Place

The study was conducted at QECH which is located in Blantyre city and it has a population of 728,285; according to the 2012 Malawi population census [44]. Besides the Blantyre city population, QECH also caters as a referral hospital for 13 districts in the Southern Region of Malawi .

4.3 Study Population

All adult patients who had bowel resection and primary anastomosis from 2008 to 2016 at QECH.

4.3 Sample size

Using the formula below, the required sample size was **138**

$$n = \frac{p(1-p)}{\left(E/1.96\right)^2}$$

where n = minimum sample size; p = expected prevalence, expressed as decimal, 0.1 in this case.; E = margin of error (expressed as a proportion); 1.96 is the Z value corresponding to 0.05 significance level.

It was anticipated to observe about 10% (0.1) of confirmed anastomotic leak rate from our population.

This is estimated with 95% confidence and having a 5% margin of error, which means that if we obtain the percentages of 5% to 15% will be consistent with the null hypothesis that the percentage is 10% with a 95% confidence.

4.4 Ethical consideration

Permission to conduct the study was sought from the College of Medicine Research and Ethics committee (COMREC) before the commencement of the study.

Since it was a retrospective study, there was no requirement for obtaining consent from the patients.

However, in order to maintain patient confidentiality, patient names were not used on data collection sheets. All the cases were assigned a code number.

4.5 Data management and analysis

Data entry was done using Windows Excel Programme. The statistical analyses were performed using statistical package for social sciences (SPSS) version 20.0 for Windows. The mean ± standard deviation (SD), median and ranges were calculated for continuous variables whereas proportions and frequency tables were used to summarize categorical variables. Chi-square (χ^2) was used to test for the significance of association between the independent (predictor) and dependent (outcome) variables in the categorical variables. The level of significance was considered as $P < 0.05$. Logistic regression analysis has been used to determine predictor variables that predict the outcome.

CHAPTER 5

4. RESULTS

Over the 9-year study period, 551 patients underwent intestinal anastomosis without faecal diversion (according to electronic data base). Out of the 551 patients recorded in the surgical electronic data base, we managed to retrieve 185 (33.6%) files from HIMS and were included in this study. The remaining 366 (66.4%) files were missing and were not included in this study.

Patient demographic information for the entire study group is outlined in Table 5.1.

Table 5 .1: Patients Demographic Data

Valuable	Overall (n =185)
Gender • Male • Female	 124 (67 %) 61 (33 %)
Age	43.06 SD 16.997(range 18-89)
ASA score • I • II • III • IV	 48 (25.9%) 79 (42.7%) 50 (27%) 8 (4.3%)
Haemoglobin level • < 10g/dl • >10g/dl	 156 (84.3%) 29 (15.7%)
Emergency • Yes • No	 175 (94.6%) 10 (5.4%)
Referral • Yes • No	 89 (48.1%) 98 (51.9%)
HIV • R • NR • UN	 17 (9.2%) 12 (6.5%) 156 (84.3%)

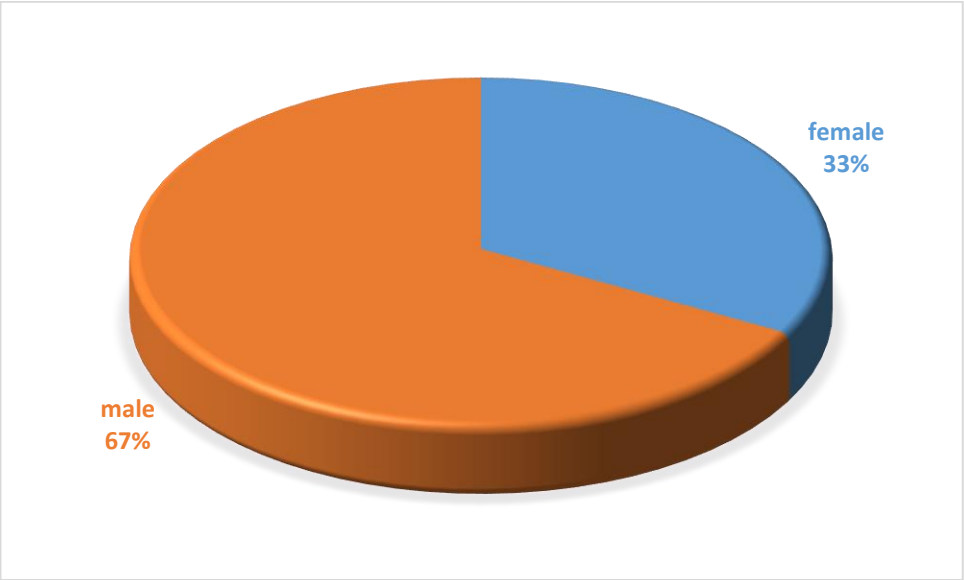

Figure 5.1: Sex distribution

Male patients represented 67 %(n= 124), while female patients were only 33 %(n= 61). These data suggest a clear male preponderance for patients who had bowel surgery with male to female ratio of 2:1.

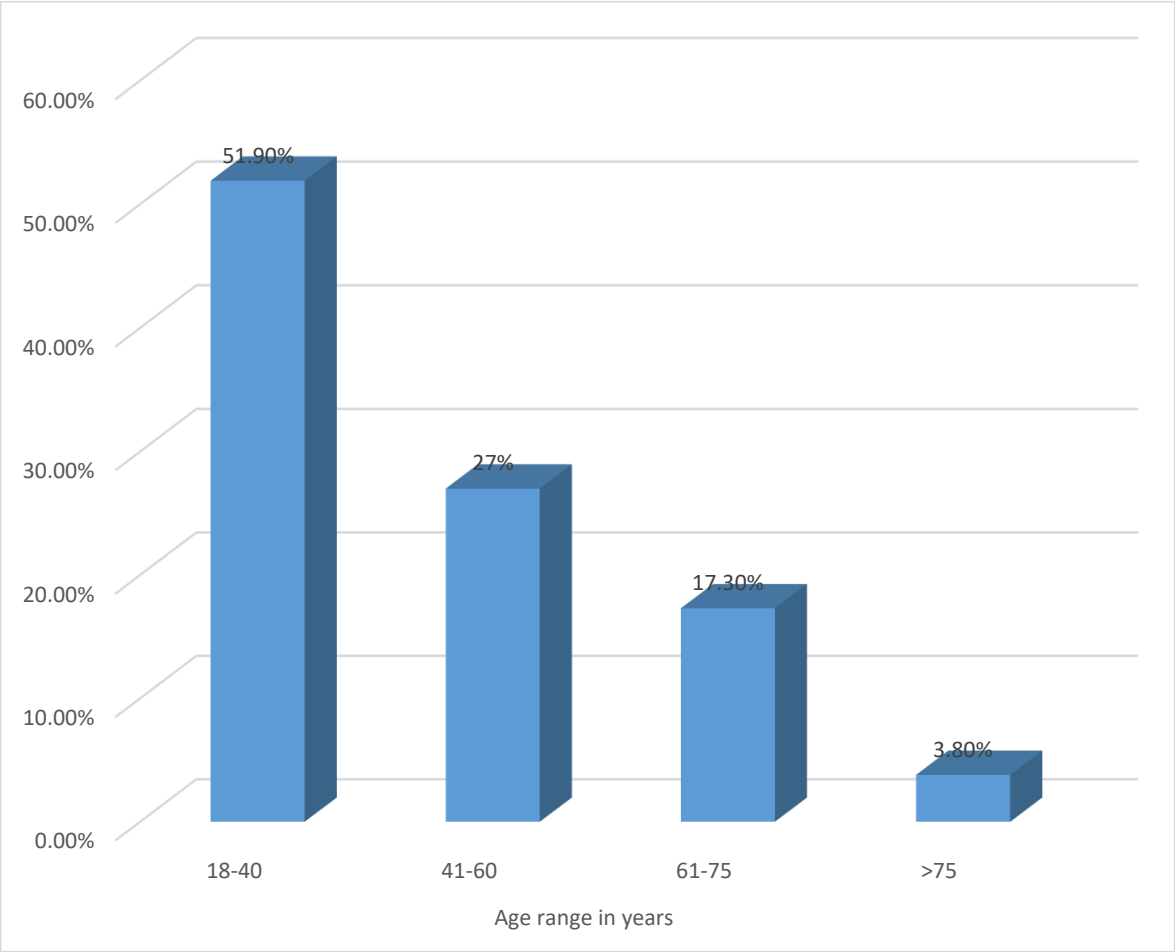

Figure 5.2: Age distribution of the study group

The mean age for the study population was 43 years with a minimum age of 18 year and a maximum age of 89 years. There were only 7 adults above the age of 75 years. The mean age for females was 28.9 years, while the mean age for males was 38.6 years.

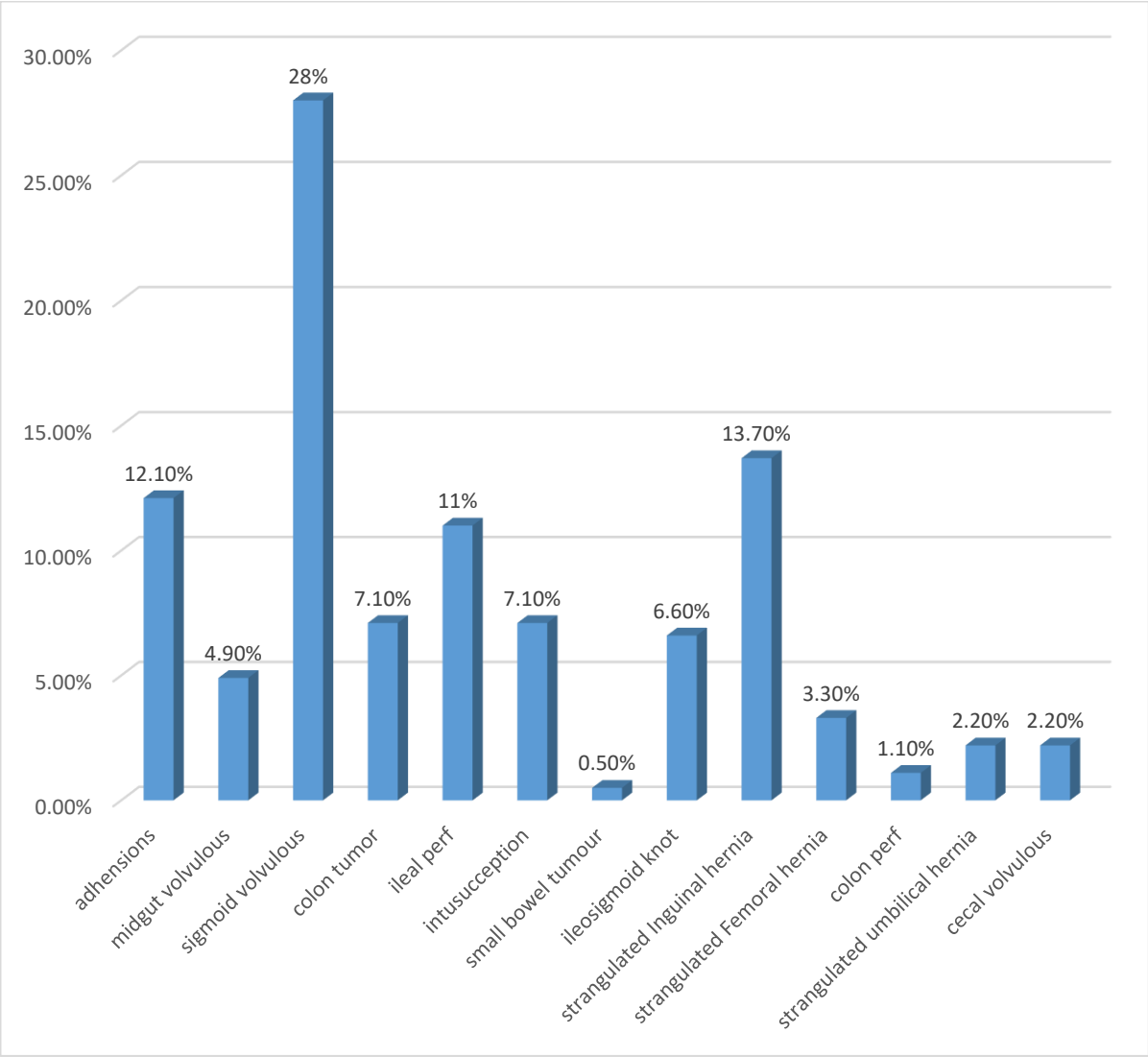

Figure 5.3 Common causes of bowel surgery

Sigmoid volvulus (28%) was the commonest cause of bowel surgery at QECH followed by strangulated inguinal hernia (13.7%) and adhesions (12%).

Table 5.2: showing the surgical management for different types of bowel pathology

Bowel surgery	Number(n=185)	Percentage
Small bowel resection and anastomosis	90	48.6
Sigmoid resection and colorectal anastomosis	65	35.1
Right colon, ileum resection and ileocolic anastomosis	30	16.2

Small bowel resection and anastomosis was the most form of surgery followed by sigmoid resection and anastomosis.

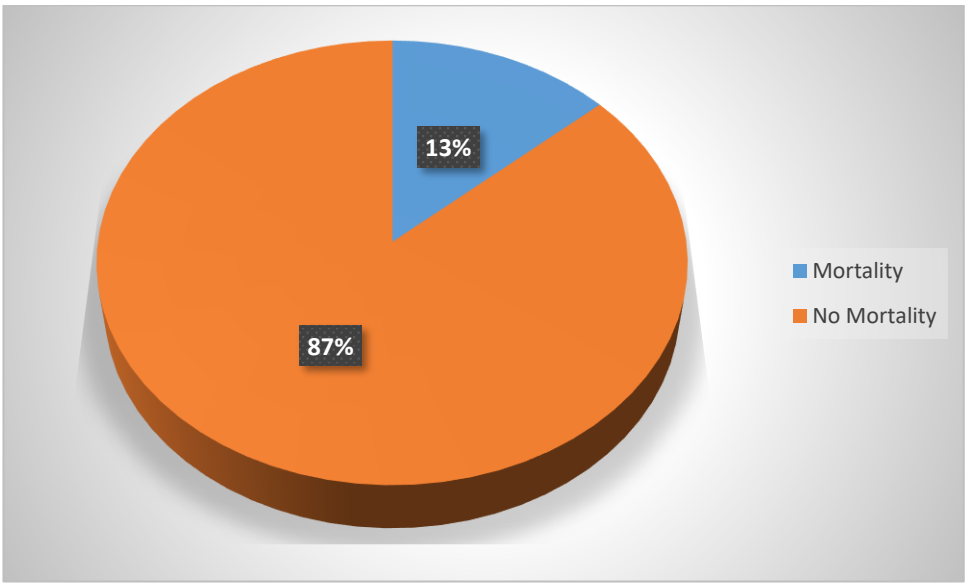

Figure 5.4: The overall mortality rate due to bowel surgery

In this study, mortality rate due to bowel surgery was 13.5 % (25/185).

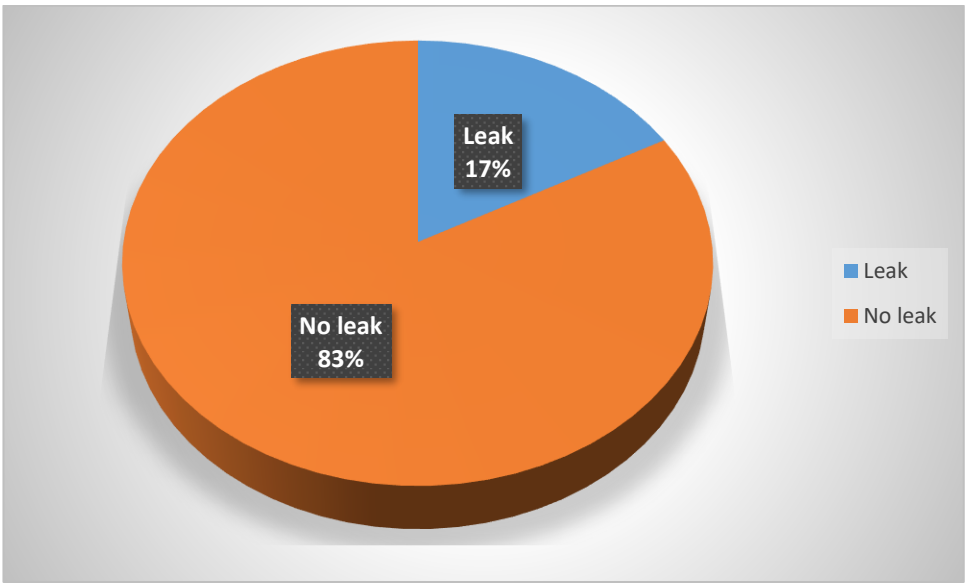

Figure 5.5. Anastomotic leak rate at QECH

Out of 185 patients who had bowel resection and anastomosis, 31 of them had anastomotic leakage representing 17 % leak rate. There were 17 males and 14 females with a mean age of 38.74 years (range 18–75). Overall, leaks were diagnosed at a mean of 6.32 days (range 3–14) postoperatively. Small bowel leak was diagnosed at a mean of 6.22days and Large bowel leak was diagnosed at a mean of 6.58days.

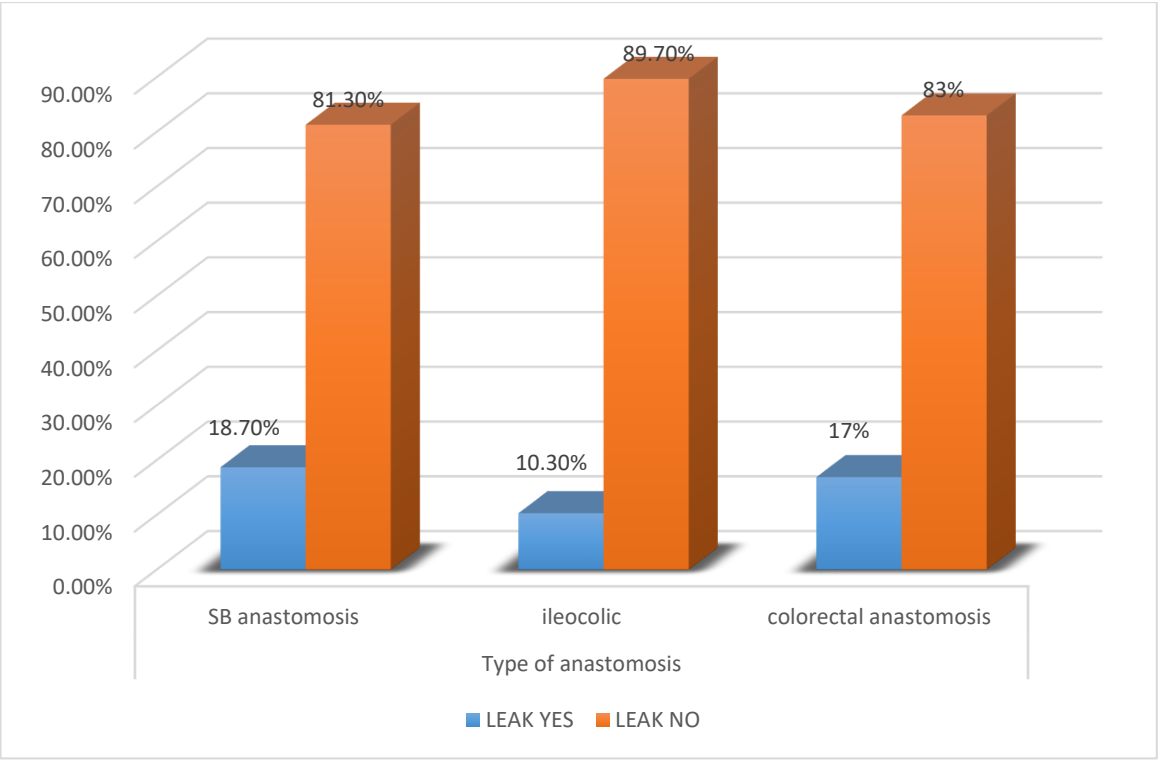

Figure 5.6: Type of bowel anastomosis and it's leak rate

There were 91 small bowel anastomoses 17 (18.7%) of them leaked, out of 29 ileocolic anastomoses 3(10.3%) and 11(17%) out 65 colorectal anastomoses leaked respectively.

There is no difference between colorectal and small bowel anastomosis with a P value of 0.864 on bivariate .

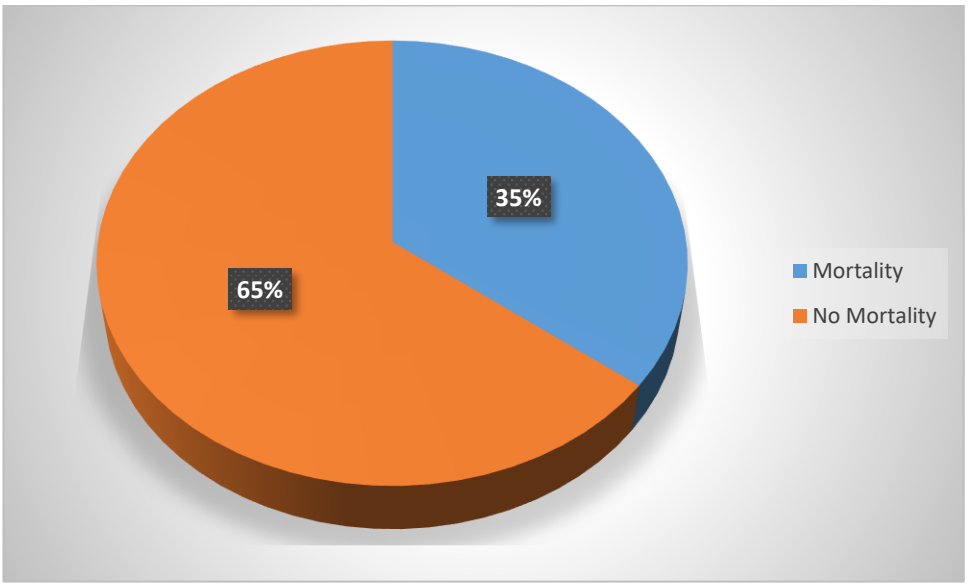

Figure 5.7: Mortality rate post bowel anastomotic leak.

Mortality rate post anastomotic leak was 35.5 %(11/31). Pearson chi-square of 15.380, exact fisher test of 0.000 and ODDs Ratio (OR) 5.5

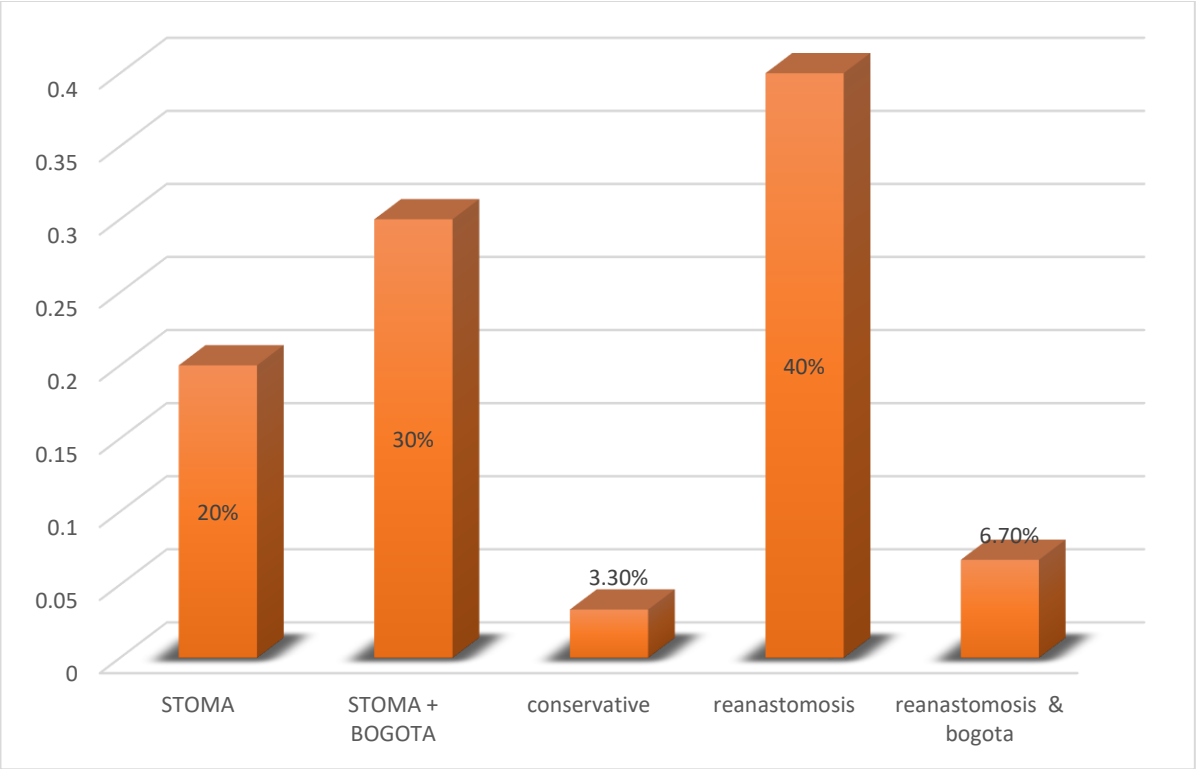

Figure 5.8 Management of the patients post anastomotic leak

Almost all the patients except one underwent another laparotomy. Fifty percent of the patients underwent abdominal washout and stoma creation followed by bowel re anastomosis (40%).

Table 5.3: Post Surgery Hospitalization period

Number of Days	Frequency	Percent
1-5	20	10.8
6-10	95	51.4
11-15	35	18.9
16-20	12	6.5
21-25	7	3.8
26-30	4	2.2
>30	12	6.5
Total	185	100.0

Approximately 70% of the patients spent 6 to 15 days in the hospital post-surgery with an overall mean of 9.73 days (range 6–79 days).

Table 5.4: Hospitalization versus anastomotic leak

LEAK		HOSPITALIZATION PERIOD							Total
		1-5	**6-10**	**11-15**	**16-20**	**21-25**	**26-30**	**>30**	
YES	Count	0	6	4	6	4	3	8	**31**
	Percentage	0.0%	19.4%	12.9%	19.4%	12.9%	9.7%	25.8%	**100.0%**
NO	Count	20	89	31	6	3	1	4	**154**
	Percentage	13.0%	57.8%	20.1%	3.9%	1.9%	0.6%	2.6%	**100.0%**
Total	**Count**	**20**	**95**	**35**	**12**	**7**	**4**	**12**	**185**
	Percentage	**10.8%**	**51.4%**	**18.9%**	**6.5%**	**3.8%**	**2.2%**	**6.5%**	**100.0%**

Table 5.4 shows the post-operative hospitalization period between leak group and a group without a leak . The mean of postoperative hospitalization period was 23,69days (range 6-79days) in a leak group and 6.94days (range 1-32days) in a group without a leak. The post-operative hospitalization period was significantly longer in the leak group, $p<0.0000$

Table 5.5: Bivariate analysis of clinical and operative factors to determine association with intestinal anastomotic leaks

Predictor	Leak %(n)	No leak %(n)	P value
Gender			0.087
• **Male**	13.7(17)	86.3(107)	
• **Female**	23.0(14)	77.0(47)	
Age group			0.074
• **18-40**	20.8(20)	79.2 (76)	
• **41-60**	16(8)	84(42)	
• **61-75**	9.6(3)	90.4(29)	
• **>75**	0(0)	100(7)	
Emergency			0.74
• **Yes**	16.6(29)	83.4 (146)	
• **No**	20 (2)	80 (8)	
HB Level			**0.000**
• **>10g/dl**	11.5 (18)	88.5 (138)	
• **< 10g/dl**	44.8(13)	55.2 (16)	
Surgeon			**0.028**
• **Expert**	10.3(9)	89.7 (78)	
• **Trainee**	22.4 (22)	77.6 (76)	
Local sepsis			**0.000**
• **Yes**	33.8(26)	66.2(51)	
• **No**	4.6 (5)	95.4(103)	
ASA grade			**0.000**
• **I& II**	10.2 (13)	89.8(114)	
• **III,IV &V**	31 (18)	69(40)	
HIV			**0.018**
• **R**	35.3(6)	64.7(11)	
• **NR**	25(3)	75(9)	
• **UN**	14.1(22)	85.9(134)	

Bivariate analysis revealed no correlation between anastomotic leakage and gender, age, emergency operation and anatomical location of anastomosis. Of the 9 parameters analysed in bivariate correlation analysis, intraperitoneal local sepsis, serum haemoglobin level (<10g/dl), level of the experience of the surgeon (specialist vs trainee) performing the anastomosis, HIV positive patient and ASA score grade (III and IV) were associated with anastomotic leak.

Table 5.6: Multivariate logistic regression analysis of the Independent risk factors of intestinal anastomotic leaks

predictor	**p value**	**Relative risk ratio**	**95.0% Confidence IntervaL**
INTRAPERITONEAL LOCAL SEPSIS	**0.000**	**7.2**	**2.81-17.5**
HAEMOGLOBIN LEVEL	**0.000**	**4**	**2.167 – 7.5**
SURGEON (TRAINEE VS SPECIALIST)	**0.017**	**1.496**	**1.143-1.957**

Of the significantly associated factors in bivariate analysis, only the presence of intraperitoneal local sepsis, low haemoglobin level (<10g/dl), and trainee surgeon were shown to be independent determinants of an anastomotic leak after intestinal anastomosis.

THE ASSOCIATIONS

Table 5.7: the association between Gender and colorectal leak

GENDER		LEAK		Total
		YES	NO	
female	Count	4	10	14
	Percentage	28.6%	71.4%	100.0%
male	Count	7	44	51
	Percentage	13.7%	86.3%	100.0%
Total	Count	11	54	65
	Percentage	16.9%	83.1%	100.0%

Fisher's Exact Test 0.232

There is no association between gender and colorectal anastomotic leak

Table 5.8: the association between the colorectal leak and the surgeon

SURGEON		LEAK		Total
		YES	NO	
Specialist	Count	1	31	32
	Percentage	3.1%	96.9%	100.0%
Trainee	Count	10	23	33
	Percentage	30.3%	69.7%	100.0%
Total	Count	11	54	65
	Percentage	16.9%	83.1%	100.0%

Fisher's Exact Test of 0.006

Trainee surgeon is an independent risk factor for colorectal anastomotic leak .

Table 5.9: The association between small bowel leak and surgeon

SURGEON		LEAK		Total
		YES	NO	
Specialist	Count	7	31	38
	Percentage	18.4%	81.6%	100.0%
Trainee	Count	10	43	53
	Percentage	18.9%	81.1%	100.0%
Total	Count	17	74	91
	Percentage	18.7%	81.3%	100.0%

Fisher's Exact Test of 1.0

The is no relationship between the surgeon either specialist or trainee and development of small bowel anastomotic leak**.**

Table 5.10: The association between referred patients and AL

REFERRAL		LEAK		Total
		YES	NO	
YES	Count	19	70	89
	Percentage	21.3%	78.7%	100.0%
NO	Count	12	84	96
	Percentage	12.5%	87.5%	100.0%
Total	Count	31	154	185
	Percentage	16.8%	83.2%	100.0%

Fisher's Exact Test 0.11.

The relationship between the referred patients and anastomotic leak is not statistically significant.

Table 5.11 :The relationship between anastomotic leak and Mortality

LEAK		Mortality		Total
		Yes	No	
YES	Count	11	20	**31**
	Percentage	35.5%	64.5%	**100.0%**
NO	Count	14	140	**154**
	Percentage	9.1%	90.9%	**100.0%**
Total	**Count**	**25**	**160**	**185**
	Percentage	**13.5%**	**86.5%**	**100.0%**

The relationship between anastomotic leak and mortality is statistically significant with a Fisher's Exact Test of 0.000, Pearson Chi-Square 15.380, likelihood Ratio 12.380 and OR 5.5, implying that the odds of dying are 5.5 times higher in the leak group than the group without a leak

CHAPTER 6

DISCUSSION OF RESULTS

Bowel anastomotic leakage is the most dreaded complication of bowel surgery and is associated with high morbidity and mortality rate. The impact of leaks on patient's life can be very disastrous, resulting in prolonged hospital stay, intensive care unit (ICU) admission, multiple operations, formation of stoma and total parental nutrition (TPN).

We recruited 185 patients in this study and 67%(n=124) of them were males and 33% (n=61) were females representing male to female ratio of 2:1. These results are different to what Trencheva et al [47] reported on. In their series from Weill Cornell Medical College–New York Presbyterian Hospital, they reported more females than males. The pathology in Europe is different from our pathology that is why there is a difference in our results.

In this study the commonest cause of bowel surgery where resection and anastomosis was performed was sigmoid volvulus (28.1%) followed by strangulated inguinal hernia (17.4%) and adhesions (12.9%). These results are different from those reported by Trencheva et al [47]. In their study, neoplasm (55%), inflammatory bowel diseases (16.4%) and Diverticulitis (14%) were the main aetiologies of bowel surgery. However, it is worth noting that the causes of bowel obstruction vary from country to country and from region to region. [48]. There is not enough literature in Africa on this topic that we could use to compare with our results.

In this study, age does not affect outcome of surgery. The Pearson correlation of 0.114 and p value of 0.121 which is not statistically significant. There is however, an increasing trend in the mortality rate as age increases; 12.5%, n =4/34, (61-70years); 42.9%, n=3/7(> 75 years). However, the population is skewed to the left; i.e. there were fewer patients in the older age-group. From age 61-90 years there were only 39 patients, representing 21.1% of the total number of patients with bowel surgery. In this study, the majority of leaks 20.8% (20/96) happened in the younger age group of (18-40 years) followed by 41-60 years representing 16% (8/50), 9.4%(3/32) of the age group of 61- 75 years. There was no leak in the age group above 75 years. These findings are in contrary with other studies where anastomotic leak was significantly high in advanced age group of 75year and above [34]. Advanced age is a known risk factor for many conditions. A big sample size is required to draw conclusions related to this observation.

Gender has been identified as a risk for colorectal AL. In a prospective study of 196 patients with rectal cancer resections, multivariate analysis showed male patients with anastomoses less than 5 cm from the anal verge had a higher rate of AL than did women [45]. Similarly, a retrospective analysis of 541 consecutive operations with colonic and rectal anastomoses found an overall leak rate of 11% in men as compared with only 3% in women, which on multivariate analysis was significant (p 0.001) [46]. In this study, overall colorectal anastomoses were 35% (65/185), out of which 21.5 %(14/65) of them were done in females and 78.5% (51/65) of them in males. In contrast to the other

studies, gender was not a risk factor for AL (female 28.6% [4/14] vs male 13.7% [7/51] Fisher's Exact Test 0.232). These observations could be due to a smaller sample size.

In this study, 53% (98/185) of bowel anastomoses were done by trainee and 47% (87/185) of anastomosis were done by specialist. Trainee had a leak rate of 22.4 %(22/98) vs 10.3% (9/87) for specialist. The Pearson Chi-Square was 4.841, Likelihood Ratio 4.995, Fisher's Exact Test 0.031 and OR 0.399 CI 95% (0.173- 0.921). Overall, the trainee in these series is a risk factor for anastomotic leak.

Various series have reported the AL rate of 2 % to 7 % for small bowel operation if the surgery was done by an experienced surgeon [22-25]. In our study, we had 91 small bowel anastomoses. Out of the 91 anastomoses 17 leaked representing 18.7% leak rate. Our anastomotic leak in small bowel surgery was very high compared to what is reported in literature, this is possibly due patients' related factors rather than surgeons factor since there was no statistical difference between the specialist' 18.4% (7/38) leak rate and Trainee 18.9% (10/51) leak rate with Fisher's Exact Test of 1.0.

In this study 35% (65/185) of bowel anastomoses were colorectal anastomoses. Out of the 65 colorectal anastomoses, 32 cases were done by specialist and 33 cases were done by trainees. There was one patient in the specialists' group who had an anastomotic leak representing 3.1 % leak rate and there were 10 patients in trainee group who had AL representing 30.3 % AL rate. The relationship is statistically significant with a P value of 0.006 OR 0.074. The overall AL in colorectal anastomoses is 16.9% (11/65). These

results are different with what is reported in a systematic review and meta-analysis of trainee- versus expert surgeon-performed colorectal resection [51].

In this meta-analysis, they compared short-term and oncological outcomes following colorectal resection performed by surgical trainees and specialist surgeons. The primary outcome in this study was anastomotic leak rate. The final analysis included 19 non-randomized, observational studies of 14 344 colorectal resections, of which 8845 (61.7 %) were performed by specialist and 5499 (38.3%) by trainees. The overall rate of anastomotic leak was 2.6 %. Compared with specialist, trainees had a lower leak rate (3.0 versus 2.0%; OR 0.72, P = 0.010) [51]. In our study a trainee is an independent risk factor for colorectal AL therefore, we recommend that an expert should always supervise or perform a colorectal anastomosis.

Another study looked at American Society of Anaesthesiologists (ASA) score Grade III to V. They did a retrospective review of 1417 patients. In that study patients, who had perioperative ASA score Grade III to V were found to have a significantly increased risk of leak after an intraperitoneal anastomosis compared with those with an ASA score Grade I to II (4.6 versus 0.8 %) [34]. In this study ASA score was correlated in the bivariate analysis (ASA score grade I and II 10.2% vs 31% in ASA score grade III and IV) and the relationship was significant (Fisher's Exact Test0.001). However, on multivariate regression, ASA score was not found as an independent risk factor for anastomotic leak.

In the same retrospective review, they found a significantly increased risk of the leak with emergency surgery after an intraperitoneal anastomosis compared with elective surgery (4.4 versus 1.0 %) [34]. For patients with both an ASA score Grade III to V and an emergency operation, the risk of an anastomotic leak was 8.1 %. In our study, 94.6 % (175/185) were emergencies and 5.4% (10/185) were elective cases. The emergency group had 16.6 %(29/175) leak rate with the p value of 0.675 implying that the emergency surgery is not a risk factor for anastomotic leak in our setting.

In this study, only 15.7% (29/185) patients were tested for HIV and 58.6% (17/29) of them were HIV positive and 12 (41.4%) patients were HIV negative. The HIV positive group had significantly anastomotic leak rate of 35.3% (6/17) vs 25% (3/12) in HIV negative group (P value of 0.018). The majority of the study patients, their HIV status were not known 84.3% (156/185). The overall HIV rate was 9.1 %(17/185), However due to a large number of case files labelled unknown HIV status, this is likely to be a gross underestimation of the total number of cases who were HIV positive. The relationship between HIV status and anastomotic leak was only proved be significant on bivariate analysis. HIV positive status was not an independent risk factor for anastomotic leak on multiple regression analysis possibly due to low numbers of the HIV tested group.

Local sepsis which in this study is defined as the presence of pus, enteric contents or gangrenous bowel in the peritonium, has been correlated on bivariate analysis and also proven on logistic regression as an independent anastomotic leak determinant. In this series, 41.6% (77/185) of bowel anastomosis were done in the presence of local sepsis,

33.8% (26/77) leaked. Pearson X2 was 27.358, Likelihood Ratio 28.272, Fisher's Exact Test 0.000 and OR of 10.502 with CI 95% (3.809- 28.956). These statistics implies that there is a strong relationship between the presence of intraperitoneal sepsis and anastomotic leak and patients with local sepsis at the time surgery had 10.5 times chance of developing anastomotic failure. It is stipulated that presence fibrinopurulent exudates in the peritoneum compromises the healing of anastomosis by filling up the anastomotic space despite rigorous lavage hence preventing fibroplasia and angiogenesis from bridging the gap as in healing by primary intention and as a result the anastomosis heals by secondary intention [53].

In this study, haemoglobin level of less than 10g/dl was correlated with leak formation. There were 29 patients with low HB (less than 10g/dl) , 13 of them leaked representing 44.8%(13/29) , the X2 for this relationship was 19.427, Likelihood Ratio 15.772, Fisher's Exact Test 0.000 and relative risk ratio of 4. These statistics implies that there is a relationship between low Hb and anastomotic failure and the chances of leak formation are 4times higher in a patient whose Hb is less than 10g/dl than a patient with Hb of more than 10g/dl. These results are similar to what is reported in literature [49, 50]. Hemoglobin is related to perfusion and oxygenation of the anastomotic margins which is an essential factor for anastomotic healing so in the presence of anaemia, oxygen carrying capacity to anastomotic tissues is reduced leading to tissue ischemia and subsequent formation of the leak.

In this study, the overall mortality rate due to bowel surgery was around 13 %(25/185) and the prevalence of AL rate was 17%(31/185). The mortality rate among patients with AL was very high as 35.5%(Pearson chi-square of 15.380, exact fisher test of 0.000 and ODDs Ratio (OR) 5.5) compared to 27% in other settings [37-41]. This implies that the relationship of AL and mortality rate is statistically significant and patients who develop an anastomotic leak in our setting are at 5.5times risk of dying than those without an AL. The reason we have high mortality rate than what is recorded in other literature could partially be explained by shortage of ICU beds and TPN. Our hospital has one ICU with 4 beds and usually patients with anastomotic leak who may have benefited from ICU management end up admitted in surgical general ward due to lack of space in our ICU. Secondly, such patients usually develop gut failure hence the need for TPN. Unfortunately, in our setting, TPN is not readily available as a result the increase in our mortality rate post AL.

In this series, the overall mean postoperative hospitalization was 9.73 days (range 6–79 days). It was significantly longer in the anastomotic leakage group: 23.69 days (range 6–79 days) versus 6.94 days (range 1–32 days) in a group without leak, $p < 0.0000$. Our findings are similar to what is published in various series where the mean length of stay in the hospital for patients with AL has been described to be between 36 and 39 days, approximately 4 times longer than for patients without leak [38,43].

CHAPTER 6

6. CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The study to look at the determinants of anastomotic failure among adult bowel surgery patients was the first of its kind to be done in Malawi. It has managed to highlight our burden of anastomotic leak at QECH unit, and the knowledge gathered from this study has bridged the knowledge gap and form the baseline data where the next studies will be built on. A number of conclusions were drawn out from study.

The prevalence of anastomotic leak was high in our setting and most leaks happened in the younger age group.

Advanced age group was not a determinant of anastomotic leak possibly due to low numbers in this study.

Gender, emergency of the operation and location of the anastomosis were not determinants of anastomotic leak.

HIV positive status and ASA score (grade II and IV) were dependent risk factors for anastomotic leak on univariate analysis but not independent predictors of anastomotic leak on regression analysis.

Intraperitoneal sepsis, serum haemoglobin level of less than 10g/dl and Trainee surgeon were independent determinants of anastomotic failure.

The mortality rate post anastomotic leak was very high 35%.

Anastomotic leak was associated with prolonged hospitalization .

6.2 Study limitations

Being a retrospective study, there were many challenges including the following:

1. Incomplete data
2. Missing files
3. Variations in the investigations and management done to patients

However, the results still provide an indication of the extent of the problem but there is need to do a prospective study so as to collect detailed information and draw more reliable conclusions.

6.3 Recommendations

There is a need to conduct a larger and prospective study. This will enable us to determine the risk factors for anastomotic leak. A prospective study will ensure validity of the findings as there will be adequate data.

The specialist should operate more with trainees and provide more guidance in intraoperative decision making and skill transfer.

A trainee should not perform a colorectal anastomosis without the presence of the specialist

Anastomosis should be avoided in the presence of intraperitoneal sepsis and whenever the perioperative serum haemoglobin is less than 10g/dl .

CHAPTER 7

7. FURTHER STUDIES REQUIRED

This research highlighted the determinants of anastomotic in patients who are managed at QECH. Since this was a retrospective study, there is need to conduct a prospective study so as to ascertain a number of issues:

1. To determine the relationship between perioperative transfusion and anastomosis leakage

2. To establish the association between HIV-AIDS and anastomotic leakage

3. To establish the relationship between serum albumin level and development of anastomotic leak .

Dissemination of findings

Results presentation

A report will be written, bound and distributed as indicated on the list below. It is in the interest of the investigator to publish the findings in a peer reviewed journal.

Distribution List

The research findings shall be sent to the following:

- The College of Medicine The College of Medicine Research and Ethics Committee (COMREC)
- College of Medicine Library
- The Health Sciences Research Committee (through the COMREC secretariat)

- The University Research and Publication Committee (URPC) through the COMREC secretariat
- The department of Infectious diseases at the MOH headquarters
- The Director, QECH
- All DHOs

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APPENDICES

Appendix 1: Data Collection Form

Date

ID

Patient's Details

Age

Sex

M	F

Area of Residence: ……

CLINICAL DATA

HISTORY

Abdominal pains

Yes	No	Duration……..

Location of pain ----------

Vomiting

Yes	No	Duration…..

Constipation

Yes	No	Duration….

Anemia

Yes	No

Fever

Yes	No	Duration…..

PAST MEDICAL HISTORY

History of abdominal Pains associated with Meals.

Yes	No	Cannot recall

History of Liver Disease

Yes	No

Diabetes Mellitus

Yes	No

HIV Status

R	NR	Unknown

Intoxications

Yes	No

Alcohol

If yes: what type, how much……

Smoking

Yes	No

<u>EXAMINATION</u>

Bp……PR……..Temp…….

Distension

Yes	No

Guarding

Yes	No

Tenderness

Yes	No

Bowel sounds

Yes	No	Scanty

Rectal Examination : presence of stool

Yes	No

DIAGNOSIS

Sigmoid volvulus

Yes	No

Perforated bowel 2nd to typhoid

Yes	No

Small Bowel Obstruction

Yes	No

Colon tumor	Yes	No
Small bowel tumor	Yes	No
Bowel perforation 2nd to trauma	Yes	No

URGENCY OF SURGERY

Elective	Yes	No
Emergency	Yes	No

PRE OP INVESTIGATIONS

Document Abdominal Xray Erect and Supine :

SBO	Yes	No
LBO	Yes	No
Erect CXR: Done: Yes/No. Documented free air under diaphragm	Yes	No

FBC: Done: Yes/No. WBC……Ly %.....NE %..... HB…….. PLT…….

MANAGEMENT

Bowel resection

Yes	No

Tick (√) appropriate box

Jejenum	
ileum	
Right colon	
Left colon	

Bowel anastomosis

Yes	No

Tick (√) appropriate box

Small bowel anastomosis	
Ileacolic anastomosis	
Colon –colon anastomosis	
Anterior resection and anastomosis	

Principle surgeon

Consultant	Yes	No
Registrar	Yes	No

.**Peritoneal cavity Operative Findings**

Gastrointestinal contents	Yes	No
Pus	Yes	No
Sigmoid volvulus	Yes	No
Midgut volvulus	Yes	No
Dead small or large bowel	Yes	No
Ileal perforation	Yes	No

	Yes	No
Colon tumor		

Outcome

	Yes	No
Anastomotic leak		

If yes how many days post-surgery

Discharge……

Death ……